

SCREEN&GO

SCREENING POLYGRAPH

USER'S MANUAL



Screen&GO Manual
Revisión: 534-70S-MU2 Rev. 1.07
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Please refer to the device's Service Manual for additional information.

This manual can be purchased through the After Sales Service.

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DISCLAIMER

SIBEL S.A. is responsible for the security, reliability and performance of this equipment only if:

- The place where the system is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
- All repairs, revisions or modifications, both in and out of the warranty period, are made by technical staff of Meditel Ingeniería Médica S.L. o SIBEL S.A.
- The system is used by qualified staff in accordance with the recommendations stated in this User's Manual.

BRANDS

Bitmed is a registered trademark of Sibel, S.A.

**PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE DIRECTIVE
93/42/EEC (CLASS IIa).**

CE 0197

Thank you for choosing this product. SCREEN&GO system is designed and manufactured with the best guarantees of quality.

Applications SCREEN&GO and its related software will open a world of possibilities in the sleep study.

If you have any possible improvement for this product, we welcome your suggestions may be directed to Customer Service Department.

Revised
Date: 2014-06
Technical Director

Approved
Date: 2014-06
Sales Director

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SAFETY

The Screen&Go respiratory polygraph has been developed by the R+D+i Department of SIBEL S.A. with the collaboration of reference Health Centers and doctors specialized in the area of Sleep Disorders.

The Screen&Go respiratory polygraph is designed and manufactured in accordance with the Quality Manual of SIBEL S.A. which is in consistency with the quality standards EN 13485 and ISO 9001 and European Directive 93/42/EEC concerning medical devices and 2007/47/EC. According to this directive the equipment is Class IIa. The Screen&Go also complies with the EN 60601.1 Electrical Safety and Electromagnetic Compatibility EN 60601.1.2 standards, as specified in the ELECTROMAGNETIC COMPATIBILITY annex.

The Screen&Go also complies with the following directives and regulations: Packaging and packaging waste directive 94/62/EC; Waste Electrical and Electronic Equipment Directive (WEEE) 2002/96/EC; Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (REACH).

INTENDED USE

Acquisition, storage and display of biomedical signals for the simplified diagnosis and control of sleep-related breathing disorders (mainly Sleep Apnea and Hypopnea Syndrome) being anyone or any combination of the following signals: respiratory airflow, snore, thoracic effort, SpO₂, beats per minute, body position, and body activity.

Next conditions must be taken into account:

- Use in a health center, patient's home or similar indoor use (not for outdoor use).
- Not intended for use in moving transport vehicles.
- Not intended for monitoring vital signals.

INDICATIONS FOR USE

The Screen&Go has been designed for maximum safety. All of the operating instructions should be read before proceeding to operate with the system. Failure to do so may result in injuries to the user or the patient and damage to the device and/or accessories.

The Screen&Go has been designed for being used by a doctor or a technician trained in the acquisition of respiratory signals and the transmission of these signals to a PC during polygraphic tests. The user is allowed to configure the device under these conditions. However, it is not recommended that the configuration of the device is changed without understanding the principles of signal digitalizing.

Minimum age of patients is 5 years, weighing over 15 kg and a minimum height of 70 cm. The medical staff will instruct the patient for a correct test execution, to avoid interferences in the measurement and to replace the sensors in case of movement. It is therefore important that the patient can understand the instructions given by medical staff.

The intended environments of use are hospitals, sleep centres and sleep clinics. Tests may also be carried out at the patient's home. In this case the patient is only authorized to start and stop the test, and should be adequately instructed by the doctor on this respect. The Screen&Go is not designed to be used outdoors, nor in other conditions or with energy sources not covered in this manual. Using the Screen&Go systems does not involve any monitoring or diagnosis of the patient.

LIMITATIONS IN USE. CONTRAINDICATION.

The interpretation of the tests and any ensuing treatment must be carried out by a doctor. The acceptability of a test is the responsibility of the health personnel.

The symptoms presented by the patient before starting any test should be considered by the health personnel.

The Screen&Go should not be used when it is likely that the validity

of the results may be compromised due to external factors (Electro Magnetic interference – see section EMC).

WARNINGS AND PRECAUTIONS

The Screen&Go IS NOT CERTIFIED FOR USE IN CONTINUOUS MONITORING, where a failure in operation may cause injuries or the death of the patient. This product does not maintain nor does it help to maintain the life of the patient. The term CONTINUOUS MONITORING is specified in regulation EN60601-1. The Screen&Go is classified as Class IIa in accordance with Directive 93/42/EEC on medical devices.

The pulse oximeter is not provided with physiological-type alarms.

The pulse oximeter is calibrated to display functional oxygen saturation and requires no calibration.

The pulse oximeter waveform is not standardized.

The Sleep&Go is not intended for monitoring vital signals.

There are no applicable parts to the patient which produce stimulation.

The system has no user-serviceable parts. Use only authorized service and spare parts supplied by the manufacturer.

Contact of liquids with the internal parts of the device and the connectors must always be avoided.

The system is only resistant to moderate splashing and dripping (Protection level IP22: protection against access to hazardous parts with a finger; protected against solid objects with a diameter of 12.5 mm and above; protected against water drops falling vertically with a maximum inclination of 15 degrees of the envelope).

Do not submerge the parts of the device in any liquid. MAY CAUSE ELECTRIC DISCHARGE.

No parts are allowed for temporary immersion.

The cleaning instructions in this manual and also in the instructions

of use of any sensor supplied but not manufactured by SIBEL S.A. must be carefully followed.

Keep your device protected from shock and vibration. During transportation, place all the items in the carrying case. The material provides enough protection against small accidental impact.

Do not use the system in and MRI environment.

The system is not designed to work in an explosive environment or in the presence of flammable anesthetics or gases of any kind. **MAY CAUSE EXPLOSION.**

This product is intended for indoor use (e.g. at the patient's home or hospital) and is not suitable for use during patient transportation.

The polygraph is not intended to be used outdoors or with other conditions or energy sources that are not covered in this manual.

The Screen&Go is not protected against defibrillation shocks. Therefore, never use a defibrillator on a patient connected to a Screen&Go system.

Do not use an electric scalpel or a high frequency surgical device while the patient is connected to any sensors of the Screen&Go.

The use of mobile phones, transmitters and similar equipment generating radio frequency emissions and placed next to the system is not allowed during the tests. Therefore, do not use the system in the presence of radio equipment (mobile phones, walkie-talkie ...). Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this manual.

Remember that when multiple devices are connected to a patient there is a risk of accumulation of leakage current. Minimize the number of devices.

Do not remove the device cover. The service and repair of the device should be carried out only by trained personnel.

The Screen&Go system is prepared to work at room temperature. Avoid exposing any part of the system to heat sources. Also avoid direct exposure to sunlight. Temperature changes cause

condensation and moisture. Before using the system, allow the device to acclimate to ambient temperature. For reference, if the temperature difference between the system and the environment is above 10° C a 20 minutes wait time in an intermediate temperature is recommended.

The polygraph should not be placed adjacent to or stacked with other equipment.

The system shall be stored and used within the temperature ranges, pressure and humidity specified in section number 3.

Artifacts in the signal may be produced as a result of ESD. A trained operator should be able to recognize these artifacts easily.

The operator must be trained to be able to recognize the differences between a biological signal and signal artifacts caused by patient movements, RF interference or poor placement of the sensors. The presence of ESD or RF devices will not lead to wrong conclusions. Unusable data is not considered a risk to the patient safety.

Cables or sensors should not surround the patient's neck, especially when the patient is a child.

The Screen&Go system does not increase the safety risk for patients with pacemakers in accordance with the EN50061 standard (Medical electrical equipment – Safety of implantable cardiac pacemakers). Before using the system in patients with pacemakers, the operator should check the documents accompanying the pacemaker with respect to its certification and requirements of use and, if necessary, contact the manufacturer.

Patients must be insistently warned that they must not open the Screen&Go or attempt to adjust it.

Sensors or accessories in bad condition should not be used.

Use only the Screen&Go with accessories and sensors provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other sensors with the Screen&Go can cause damage to the device or the quality of the signals.

Sensors should be handled by their strongest parts, which are the connectors. Also, they should not get wet or exposed to very

abrupt changes of temperature. To clean the sensors, do not use abrasive chemicals. Do not apply excessive stress to the sensors. In particular, avoid bending any part of the sensors. This means that the material should not bend more than necessary in normal use.

The polygraph is designed to be used exclusively by medical staff, who should be supervised and instructed by a physician.

Medical personnel should inform the patient about precautions to be found in the WARNINGS AND PRECAUTIONS section and to be taken when using the equipment.

Use the provided carrying case when transporting the device and its accessories.

Do not reuse single-use accessories as there is risk of infection to the patient.

In case of doubt or unexpected event contact the manufacturer. You can find contact details on page 2 of this manual.

The use of nasal cannulas is not recommended in pregnant women or children, because they contain phthalates.

Do not leave the batteries inside the device if it won't be used for a long period of time.

Ensure to perform the acquisition of signals in an acoustic and light environment that allows the patient to sleeping normally.

DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION



Never dispose of the Screen&Go, its accessories and its batteries in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your country.

- Materials according to the RoHS Directive 2011/65/UE. Conform from July 22th, 2014.
The device uses a lithium battery and could use an optional NiMh battery.

For devices commercialised before July 22th, 2014: Sleepsense sensors may contain PBB and PBDE.

- Materials according to the Medical Device Directive: two of the sensors that may be used in combination with the device, contains phtalates (Sleepsense nasal cannula and Pro-Tech nasal cannula). The device and all the accesories are latex free.
- Materials according to the REACH regulation: neither the device nor its accessories use any hazardous substance according to REACH regulation.
- In the event that the device or its accessories are infected at the time of recycling, it must be disinfected or disposed by following the national regulations regarding the disposal of infected products.

Information on proper disposal is available from your dealer or from Technical Support at SIBEL S.A.

1. INSTRUCTIONS OF INSTALLATION AND USE

1.1. OPTIONS

The Screen&Go screening polygraph is available with the the following features:

Channels		Screen&Go
Nasal cannula	Airflow	
	Snore	
Auxiliary		
External Xpod	SpO ₂	
	BPM	
Body position		
Activity		
Marks		



Default



Option

1.2 PACKING LIST

RELACIÓN DE CONTENIDO / PACKING LIST SCREEN&GO/SLEEP&GO

534-708-120 REV. 4

2014-06

MODELOS/ MODELS

CÓDIGO CODE	CANT. QTY.	DESCRIPCIÓN DESCRIPTION	SCREEN&GO	SLEEP&GO	
				A	B
POLÍGRAFO / POLYGRAPH					
_____	1	SCREEN&GO/SLEEP&GO SN: 347 - _____			
Accesorios Estándar / Standard Accessories					
06312	1	BANDA DE SUJECIÓN TAMAÑO GRANDE (L) / FASTENING BELT LARGE SIZE (L)			
08049	1	CÁNULA DESECHABLE NASAL / DISPOSABLE NASAL CANNULA			
08087	1	MÓDULO TERMOPAR (INCLUYE ACTIVACIÓN DEL CANAL) / THERMOCOUPLE MODULE (INCLUDES CHANNEL ACTIVATION)			
06309	1	• SENSOR TERMOPAR / THERMOCOUPLE SENSOR			
08088	1	MÓDULO DE ESFUERZO TORÁCICO INDUCTIVO (INCLUYE ACTIVACIÓN DEL CANAL) / INDUCTIVE THORACIC EFFORT MODULE (INCLUDES CHANNEL ACTIVATION)			
06314	1	• INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO TORÁCICO / THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE			
01420	1	• BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XL) / ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)			
07678	1	• ANILLA SUJECIÓN / FASTENING RING			
08089	1	MÓDULO DE ESFUERZO ABDOMINAL INDUCTIVO PARA SLEEP&GO (INCLUYE ACTIVACIÓN DEL CANAL) / INDUCTIVE ABDOMINAL EFFORT MODULE FOR SLEEP&GO (INCLUDES CHANNEL ACTIVATION)			
06308	1	• INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO ABDOMINAL / ABDOMINAL EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	---		
01420 (*)	1 (*)	• BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XL) / ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)			
07678	1	• ANILLA DE SUJECIÓN / FASTENING RING			
08090	1	CANAL AUXILIAR (MOVIMIENTO EXTREMIDADES) PARA SLEEP&GO (INCLUYE ACTIVACIÓN DEL CANAL) / AUXILIARY CHANNEL (LIMB MOVEMENT) FOR SLEEP&GO (INCLUDES CHANNEL ACTIVATION)	---		
06310	1	• KIT SENSOR MOVIMIENTO EXTREMIDADES / LIMB MOVEMENT SENSOR KIT			
08091	1	CANAL AUXILIAR (RONQUIDO) PARA SLEEP&GO (INCLUYE ACTIVACIÓN DEL CANAL) / AUXILIARY CHANNEL (SNORING) FOR SLEEP&GO (INCLUDES CHANNEL ACTIVATION)	---		
06346	1	• SENSOR RONQUIDO PIEZOELECTRICO / PIEZOELECTRIC SNORE SENSOR			
08060	1	TARJETA MEMORIA MICRO SD CON ADAPTADOR SD / MICROSD MEMORY CARD WITH SD ADAPTER			

(*) CUANDO SE ENTREGA LA REFERENCIA 08089 JUNTO CON UN SCREEN/SLEEP&GO NO SE INCLUYE LA REFERENCIA 01420 (PAQUETE DE 2 BANDAS INDUCTIVAS TAMAÑO XL), PUESTO QUE YA ESTÁ INCLUIDA EN LA REFERENCIA 08088. LA REFERENCIA 01420 SE INCLUIRÁ SÓLO SI EL MÓDULO 08089 SE SUMINISTRA POR SEPARADO.
WHEN THE REFERENCE 08089 IS SUPPLIED WITH A SCREEN / SLEEP & GO DOES NOT INCLUDE REFERENCE 01420 (PACK OF 2-BAND INDUCTIVE SIZE XL), SINCE IT IS ALREADY INCLUDED IN THE REFERENCE 08088. THE REFERENCE 01420 IS INCLUDED ONLY IF THE MODULE 08089 IS DELIVERED SEPARATELY.

RELACIÓN DE CONTENIDO / PACKING LIST

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SCREEN&GO/SLEEP&GO

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03673	2	PILAS ALCALINAS AA 1.5V / AA 1.5V ALKALINE BATTERY			
08011	1	MALETÍN TRANSPORTE SCREEN&GO CARRYING CASE SCREEN&GO		---	---
08010	1	MALETÍN TRANSPORTE SLEEP&GO / CARRYING CASE SLEEP&GO	---		
08070	1	CD SOFTWARE BITMEDLAB (CON LICENCIA) / CD BITMEDLAB SOFTWARE (WITH LICENSE)			
	1	• MANUAL DE USO / USER'S MANUAL (Doc.534-740-MU_)			
08072	1	• MÓDULO BASE DE DATOS / DATABASE MODULE			
08071	1	• MÓDULO ANALISIS AUTOMÁTICO EVENTOS / AUTOMATIC EVENTS DETECTION MODULE			
	1	SCREEN&GO MANUAL DE USO / SCREEN&GO USER'S MANUAL (Doc. 534-70S-MU_)		---	---
	1	SLEEP&GO MANUAL DE USO / SLEEP&GO USER'S MANUAL (Doc. 534-7AB-MU_)	---		
	1	GUÍA RÁPIDA SCREEN - SLEEP&GO / SCREEN-SLEEP&GO QUICK GUIDE (Doc. 534-7AB-GR_)			
Accesorios Opcionales / Optional Accessories					
08094	1	LECTOR TARJETAS MEMORIA USB PARA PC / USB MEMORY CARD READER FOR PC			
08073	1	MÓDULO BITMED VISION PARA BITMEDLAB / BITMED VISION MODULE FOR BITMEDLAB	---		
06976	1	KIT DE PULSIOXIMETRÍA ADULTOS PARA SCREEN&GO- SLEEP&GO (Canales: SPO ₂ , BPM) / ADULT PULSE OXIMETRY KIT FOR SCREEN&GO-SLEEP&GO (Channels: SpO ₂ , BPM)			
08098	1	• MÓDULO PULSIOXIMETRÍA XPOD / XPOD PULSE OXIMETRY MODULE			
08012	1	• SENSOR PULSIOXIMETRÍA SOFT (ADULTO) / SOFT PULSE OXIMETRY SPO ₂ SENSOR (ADULT)			
07677	1	• MUÑEQUERA DE SUJECCIÓN / WRISTBAND			
08069	1	KIT DE PULSIOXIMETRÍA PEDIÁTRICO PARA SCREEN&GO/SLEEP&GO (Canales: SPO ₂ , BPM) / PEDIATRIC PULSE OXIMETRY KIT FOR SCREEN&GO/SLEEP&GO(Channels: SpO ₂ , BPM)			
08098	1	• MÓDULO PULSIOXIMETRÍA XPOD / XPOD PULSE OXIMETRY MODULE			
08013	1	• SENSOR PULSIOXIMETRÍA SOFT (PEDIÁTRICO)/ SOFT PULSE OXIMETRY SPO ₂ SENSOR (PEDIATRIC)			
07677	1	• MUÑEQUERA DE SUJECCIÓN / WRISTBAND			
08078	1	OPCIÓN FIRMWARE CANAL DE RONQUIDO POR PRESIÓN / PRESSURE SNORING CHANNEL FIRMWARE OPTION			
08079	1	OPCIÓN FIRMWARE CANAL DE POSICIÓN CORPORAL / BODY POSITION CHANNEL FIRMWARE OPTION			
08080	1	OPCIÓN FIRMWARE CANAL DE ACTIGRAFÍA / ACTIGRAPHY CHANNEL FIRMWARE OPTION			
08081	1	OPCIÓN FIRMWARE CANAL DE MARCAS DEL PACIENTE / PATIENT'S MARKS CHANNEL FIRMWARE OPTION			
08082	1	OPCIÓN FIRMWARE CANAL DE PRESIÓN CPAP / CPAP PRESSURE CHANNEL FIRMWARE OPTION	---		
08083	1	OPCIÓN FIRMWARE CANAL DE ONDA DE PULSO / PULSE WAVE CHANNEL FIRMWARE OPTION	---		
08084	1	OPCIÓN FIRMWARE MÓDULO BLUETOOTH / BLUETOOTH MODULE FIRMWARE OPTION	---		
08022	1	MÓDULO DE SENSORES EXG / EXG SENSOR MODULE	---		
08251	1	• PIEZA ANTI APERTURA TAPA BATERÍAS / BATTERY COVER BLOCKING PIECE			

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RELACIÓN DE CONTENIDO / PACKING LIST

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08085	1	KIT DE ELECTRODOS EEG PARA SLEEP&GO / EEG SENSOR KIT FOR SLEEP&GO	---		
08701	1	• ELECTRODO CUCHARA ORO EXG (PAQUETE 10U) / EXG GOLD CUP ELECTRODES (PACKAGE 10PC)			
01644	3	• CABLE ADAPTADOR 1MM A 1.5MM / CABLE ADAPTER 1MM TO 1.5MM			
02741	3	• PUENTE DE INTERCONEXIÓN / INTERCONNECTION BRIDGE			
08086	1	KIT DE ELECTRODOS ECG PARA SLEEP&GO / EKG SENSOR KIT FOR SLEEP&GO	---		
08093	1	• CABLES PARA ELECTRODOS DE CORCHETE (PAQUETE 10U) / CABLES FOR BUTTON STUD TYPE ELECTRODES (PACKAGE 10 PC)			
01027	1	• ELECTRODO DE ECG (PAQUETE 50 un.) / ECG ELECTRODE (PACKAGE 50 units)			
01644	3	• CABLE ADAPTADOR 1MM A 1.5MM / CABLE ADAPTER 1MM TO 1.5MM			
06346	1	SENSOR RONQUIDO PIEZOELECTRICO / PIEZOELECTRIC SNORE SENSOR	---		
07679	1	CÁNULA NASAL DESECHABLE PROTECH (PAQUETE DE 60u) / DISPOSABLE PROTECH NASAL CANNULA (PACK OF 60u)			
07680	1	CÁNULA ORO-NASAL DESECHABLE PROTECH (PAQUETE DE 30u) / DISPOSABLE PROTECH ORO-NASAL CANNULA 40cm (PACK OF 30u)			
07681	1	CÁNULA ORO-NASAL DESECHABLE SLEEPSENSE (PAQUETE DE 5u) / DISPOSABLE SLEEPSENSE ORO-NASAL CANNULA 60cm (PACK OF 5u)			
08049	1	CÁNULA NASAL DESECHABLE SLEEPSENSE / DISPOSABLE SLEEPSENSE NASAL CANNULA			
06311	1	BANDA DE SUJECIÓN TAMAÑO PEQUEÑO (S) / FASTENING BELT SMALL SIZE (S)			
06313	1	BANDA DE SUJECIÓN TAMAÑO EXTRA GRANDE (XL) / FASTENING BELT XTRA LARGE SIZE (XL)			
01425	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO PEQUEÑA (S) / ELASTIC INDUCTIVE BAND SMALL SIZE (S)			
01424	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO MEDIANA (M) / ELASTIC INDUCTIVE BAND MEDIUM SIZE (M)			
01421	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO GRANDE (L) / ELASTIC INDUCTIVE BAND LARGE SIZE (L)			
01420	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XL) / ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)			
01417	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA EXTRA GRANDE (XXL) / ELASTIC INDUCTIVE BAND XTRA XTRA LARGE SIZE (XXL)			
08701	1	ELECTRODO CUCHARA ORO EXG (PAQUETE 10u) / EXG GOLD CUP ELECTRODES (PACK OF 10u)	---		
08093	1	CABLES PARA ELECTRODOS DE CORCHETE (PAQUETE DE 10u) / CABLES FOR BUTTON STUD TYPE ELECTRODES (PACK OF 10u)	---		
01027	1	ELECTRODO DE ECG (PAQUETE DE 50u) / ECG ELECTRODE (PACK OF 50u)	---		

☒ ESTANDAR
STANDARD

☐ OPCIONAL
OPTIONAL

 --- NO DISPONIBLE
NOT AVAILABLE

RELACIÓN DE CONTENIDO / PACKING LIST**534-708-120 REV. 4****SCREEN&GO/SLEEP&GO**

2014-06

ADVERTENCIA:

- LOS ARTÍCULOS Y CANTIDADES RELACIONADAS ANTERIORMENTE HAN SIDO CUIDADOSAMENTE COMPROBADAS. EN CASO DE FALTAS O DESPERFECTOS PROCEDAN A COMUNICÁRNOLO LO MAS PRONTO POSIBLE.
- SI DETECTA CUALQUIER DAÑO EN EL EMBALAJE, CONTACTE CON SU DISTRIBUIDOR ANTES DE PROCEDER A LA INSTALACIÓN DEL EQUIPO.
- NO SE DEBE DESPRENDER DE LOS EMBALAJES, BOLSAS, ETC. HASTA QUE VERIFIQUE TOTALMENTE EL CORRECTO FUNCIONAMIENTO DEL EQUIPO.
- EN CASO DE DEVOLUCIÓN DE MATERIAL O EQUIPO EN DEPOSITO, ROGAMOS NOS LO ENVÍEN EN PERFECTO ESTADO, COMPLETO DE ACCESORIOS Y DEBIDAMENTE EMBALADO. CUALQUIER DESPERFECTO OCASIONADO PROVOCARÍA UN CARGO CORRESPONDIENTE EN LA REPARACIÓN O EN LA REPOSICIÓN.

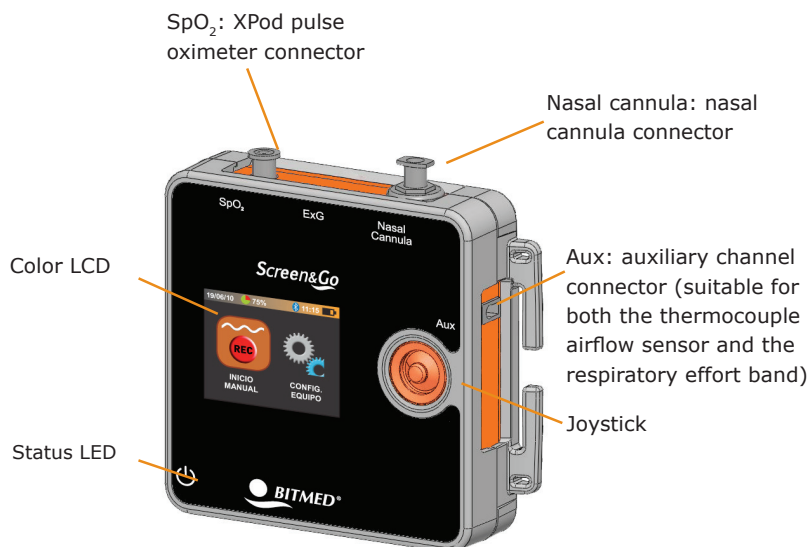
WARNING:

- *THE ITEMS AND QUANTITIES RELATED BEFORE HAVE BEEN CAREFULLY CHECKED. IN CASE OF ANY PART IS MISSING OR IS DAMAGED, NOTIFY US AS QUICKLY AS YOU CAN.*
- *IF YOU DETECT ANY DAMAGE IN THE PACKAGING, CONTACT WITH YOUR DISTRIBUTOR BEFORE PROCEEDING TO INSTALL IT.*
- *DO NOT THROW AWAY THE PACKAGING, BAGS, ETC. UNTIL THE CORRECT FUNCTIONING OF THE DEVICE IS VERIFIED*
- *IN THE CASE OF RETURNING THE GOODS, IT WILL BE APPRECIATED THAT YOU SEND THE DEVICE IN PERFECT ORDER, WITH ALL THE ACCESSORIES AND PROPERLY PACKAGED. ANY DAMAGE SUFFERED WILL MAKE A CHARGE CORRESPONDING TO REPAIR OR NEW PARTS.*

PREPARADO / PREPARED BY:**FECHA / DATE:**

1.3 LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS

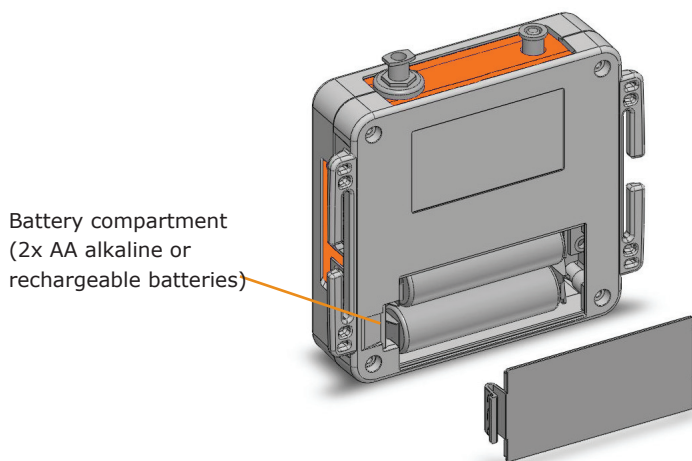
1.3.1 FRONT/TOP/RIGHT PANNELS



1.3.2 LEFT PANNEL



1.3.3 REAR PANNEL



1.4 INSTALLATION AND START-UP

This system is made of solid-state professional components manufactured under stringent quality controls. However, accidents may occur during the transportation or storage, being convenient an initial checking of the device and accessories prior to installation. If you detect a deterioration in the package, please contact the transport company and your supplier immediately, prior to installation. Do not dispose the packaging until completely verifying the proper functioning of the system.

Use only accessories described in this manual. The use of not recommended accessories could adversely affect both the patient safety and the equipment.

1.4.1 BATTERY PLACEMENT

The Screen&Go system uses two 1.5V AA batteries. You can use alkaline or rechargeable batteries with, at least, 2450mA/h. Using smaller capacity batteries diminishes the autonomy. The autonomy in normal use is about 24 hours.

The battery compartment is located on the rear panel, protected by a cap that needs to be removed to proceed to change the batteries.



Before opening the battery compartment to replace the batteries please switch off the Screen & Go.

1.4.2 POWER SAVING MODE

To save power, the device switches off the display after 50 seconds of inactivity (even if it is running a test) and the whole device after 5 minutes if the user does not start a test nor interacts with the joystick.

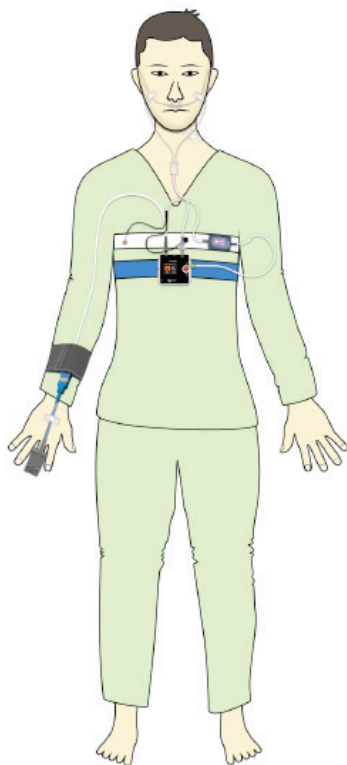
1.4.3 PLACEMENT OF SENSORS

1.4.3.1 PLACEMENT OF THE SCREEN&GO POLYGRAPH

The small size and weight of the Screen&Go system allows the patient to wear it comfortably fastened with a strap. Follow these steps to fasten the device to the patient:

- Insert the strap between the two guides in the rear side of the Screen&Go.
- Place the device on the patient's chest, in a comfortable position midway between the thoracic effort band (which should be on top) and the abdominal effort band (which should be below).
- Secure the strap by means of the Velcro so that the device stands firm.

General placement schema



1.4.3.2 NASAL CANNULA

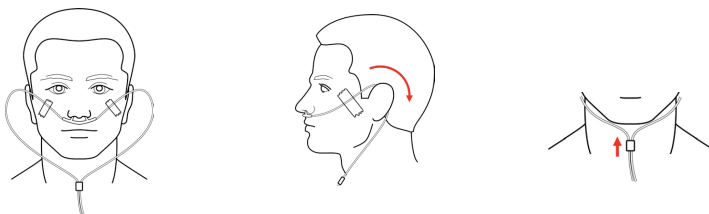
The nasal airflow cannula (refs. 07679, 07680, 07681, 08049) is used to acquire the airflow and snoring signals, by means of the device's internal pressure transducer.

The placement of the nasal cannula has a significant impact in obtaining high quality signals. Follow these steps to place it properly:

- Place the cannula over the upper lip. Bend the nasal probes softly until the tips are exposed to the maximum possible air flow. The tips should not get in contact with the skin or

penetrate the nasal orifice.

- Wrap the tube around the ears and place it under the chin. Surgical tape can be used to fasten the tubes to the cheeks of the patient. If necessary, adjust the tubes under the chin.
- Insert the cannula connector in the Luer connector of the Screen&Go (labeled as "Nassal cannula") and turn it until secured.



1.4.3.3 THERMOCOUPLE AIRFLOW SENSOR

In addition to the nasal cannula, the Screen&Go may also use the thermocouple sensor (ref. 06309) in order to measure the respiratory airflow. Both the thermocouple airflow sensor and the effort band are to be connected to the connector labeled as "Aux" and therefore both can not be used at the same time.

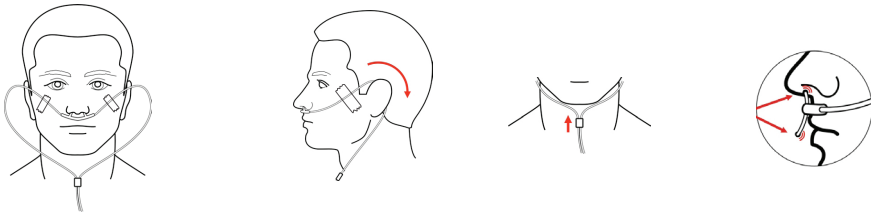
The quality of the registered signal depends on variables such as the filters selected in the software, the sensor placement, the patient's respiration and room temperature. Filters can reduce the noise in the respiratory signal, but they can also add distortion to the signal if used in excess. Filters are applied in the BitmedLab software. Read that software's manual if you need to modify them.

The placement of the thermocouple sensor has a significant impact in obtaining high quality signals. Follow these steps to place it properly:

- Place the thermocouple on the upper lip. Bend the nasal tips softly until the ends of the sensor are exposed to the maximum possible air flow. The tips should not get in contact with the

skin or penetrate the nasal orifice.

- Wrap the cable around the ears and place it under the chin. Surgical tape can be used to fasten the cables to the cheeks of the patient. If necessary, adjust the sensor cable on the chin.
- Bend the oral probe softly in its position in front of the mouth, so that the end of the sensor is exposed to the greatest oral flow possible, approximately 1 cm from the mouth. The probe should not touch the skin or the lips, nor penetrate the oral cavity.



- Insert the sensor connector in the connector of the Screen&Go labeled as "Ther".

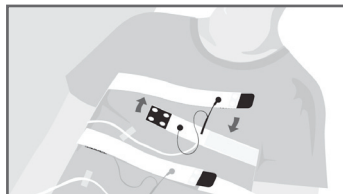
The ambient temperature affects the magnitude of the signal. If the temperature is similar to the patient's temperature, the signal level may be very low. On the other side, if the ambient temperature is very different from the patient's temperature, the signal level will be higher.

1.4.3.4 RESPIRATORY EFFORT BAND

The inductive plethysmography belt (refs. 01425, 01424, 01421, 01420, 01417) supplied with the Screen&Go is based in the RIP technology (Respiratory Inductive Plethysmography).

- Strap the sensor band around the patient's chest or abdomen, over any clothing.
- Attach the first wire of the interfaze box (ref. 06314) to the snap that is on the same side of the band as the Velcro patch.
- While holding this end to the left of the patient's center line, wrap the band around the patient's chest or abdomen.

- Pull the other end over the first end and secure the band on the right side of the center line. The band should be snug but not too tight.
- Attach the second wire to the exposed snap.



Make the connection and disconnection of the snaps with the interface box disconnected from the computer.

- Both the thermocouple airflow sensor and the effort band are to be connected to the connector labeled as "Aux" and therefore both can not be used at the same time.
- Fix each of the little boxes to the corresponding belt with the aid of the provided strips.

1.4.3.5 PULSE OXIMETER

The system is able to provide the pulse wave, as well as the measurement of the pulse rate and the functional oxygen saturation, based on the technology developed by Nonin Medical Inc. The external pulse-oximeter (named XPod) (ref. 08098) is to be connected on the top side of the device. The SpO₂ sensor is to be connected on the free end. Pay special attention to the sensor being used. Please consult the manufacturer before using non-recommended sensors.

In adults, the ideal point for the application of the oximeter sensor is the index finger. However, it may also be placed in other fingers when the thickness is between 5mm and 21mm (0.2" and 0.8"), (dimension "H" in the figure).

To place pulse oximeter sensor, follow these steps:

- Place the wristband provided in the patient's wrist and insert the XPod module into the socket.
- Insert a finger (preferably the index finger) in the sensor until the finger tip reaches the stop. It is not recommended to place

this sensor in the thumb. Keep the fingernail of the patient pointing toward the top side of the sensor. Make sure that long fingernails do not interfere with the adequate positioning of the finger.

- To obtain the best results, fasten the cable to the finger, using surgical tape, preferably around the base of the finger. Make sure that the tape fastening the cable does not restrict blood circulation.
- Take the cable coming out of the wristband over the arm and connect it to "SpO₂" of Screen&Go.



Furthermore, the following conditions of use should be observed:

- The oximeter must not be used by itself to reach important medical conclusions. Medical caution must always be taken and other means must be used, whenever possible, for confirmation.
- Incorrect use or inappropriate handling of the sensor can cause damage to the sensor or cable. This would lead to incorrect measurements and readings.
- Remove nail polish or artificial nails before applying the sensor, as they could cause incorrect readings.
- The sensors cannot be sterilized. Do not submerge the sensors in liquid. The sensors must be disconnected from the Screen&Go prior to cleaning or disinfection.
- The operation of the oximeter sensor may be affected by the presence of strong room lighting. If necessary, the sensor area must be protected (e.g. with surgical tape).
- The oximeter may not be capable of detecting minimal values of saturation with the same degree of accuracy and precision as the maximum values of saturation. It is also possible that it can not quantify the degree of existing hyperoxemia.

- Interferences such as movements, abnormal hemoglobins, intravascular contrasts, states of low perfusion and skin pigmentation may affect the operation of the pulse oximeter.
- It is unlikely that organisms are transmitted via pulse oximetry. However, we recommend washing the pulse oximetry sensor for each change of patient with soapy water or disinfectant solution as specified by the manufacturer.
- The pulse oximetry module and the pulse oximetry probe is CE marked. The temperature of the area of the probe in contact with the finger will not reach temperatures $> 42^{\circ}$.
- See the instructions for use before use. Strictly follow the manufacturer's safety instructions, as well as those specified in this manual.
- The maximum recommended time of application of an pulse oximeter in the same place is 24 hours. The point of placement must be checked frequently to determine the position, circulation and cutaneous sensitivity of the patient. Reaction to the sensors by the patients may be different depending on their state of health and skin condition. Adhesive material must not be used if the patient shows an allergic reaction to such material.
- For long-term measurements, it is recommended to use flexible or disposable sensors.
- The adult sensor is for people over 12 years of age ($>40\text{Kg}$). The pediatric sensor is for children aged between 5 and 12 years of age (15-40 kg).
- The system can measure the pulse rate and functional oxygen saturation. A functional meter can not be used to evaluate the accuracy of a pulse oximetry sensor or a pulse oximetry monitor.
- Do not use blood flow restrictors because they can lead to loss of signal.

1.4.3.6 BODY POSITION AND ACTIVITY

The Screen&Go records information about the patient's body

position and actigraphy. Both sensors are placed inside the Screen&Go device, so no external accessory is needed.

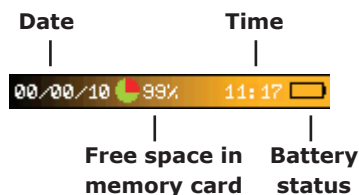
1.4.3.7 EVENT MARKER

During the test (either online or in holter mode), the patient is allowed to make a mark by simply pressing the joystick for at least 3 seconds. After these 3 seconds the screen lights on and the mark is registered. These marks are used to indicate certain events, such as the patient getting up to the bathroom, taking medication and so on.

2. OPERATION

The Screen&Go is fitted with a color screen and a joystick to interact with the options exposed by the device's software.

The top part of the screen displays an info bar with the device status at any time:



This is the screen displayed when the Screen&Go is switched on:



This screen displays status information and enables starting a new test in holter mode. The icon "MANUAL START" is selected by default. The patient can not modify the device configuration.

Use the joystick to navigate through the different screens that will be introduced. The joystick supports four directions (↑, ↓, →, ←), while pressing it is used to click an option.

2.1 WORKING MODES

The Screen&Go works always in holter mode. In this mode the Screen&Go stores the tests in a memory card. Later, the tests are transferred to the computer for evaluation. It is designed for home use or at the hospital or clinic. There are two ways of starting a test in holter mode:

- a. Manual start and stop: the patient starts and stops manually the recording of the test, through the color

screen and joystick in the Screen&Go.

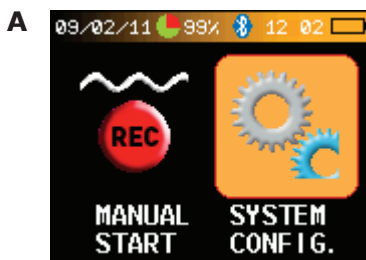
- b. Automatic start and stop: health personnel program the Screen&Go to start and stop automatically the test at a certain date and time.

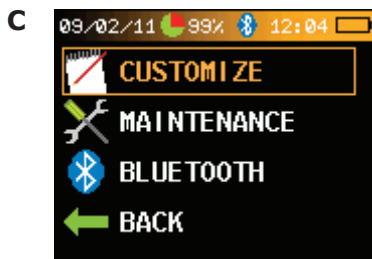
The device's batteries last up to 24 hours with a single charge.

2.2 SYSTEM CONFIGURATION

The setup mode in the Screen&Go is designed to change the device configuration (date and time, language, type of batteries used) and schedule new tests. Only healthcare personnel should access the device settings. To enter to the setup menu of the Screen&Go do the following:

- Switch on the Screen&Go and make the following keystrokes on the joystick, one after another and leaving a short interval of time between each of them: ↓, ↓, ↑, ↑.
- The screen changes and a new icon is displayed: "SYSTEM CONFIG." (A). Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.
- Select "MORE OPTIONS" (B).
- Select "CUSTOMIZE" (C).





2.3 INITIAL DEVICE SETUP

2.3.1 SETTING THE DATE AND TIME

Once in the "CUSTOMIZE" screen, follow these steps in order to change the date and time in the Screen&Go:

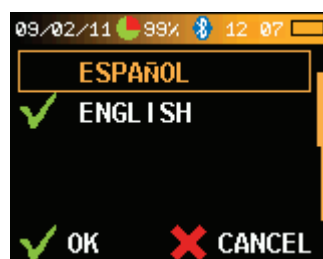
- Select "DATE AND TIME".
- Use ↑ and ↓, and ✓ to access each of the options to set the date and time in the device. Use ↑ and ↓ to modify the values in each field.
- Once you have set the date and time select "OK." To cancel setting the date and time select "CANCEL".



2.3.2 SETTING THE LANGUAGE

Once in the "CUSTOMIZE" screen follow these steps in order to change the language in the Screen&Go:

- Select "LANGUAGES".
- Use ↑ and ↓ move along the different available languages. The selected language is marked with the ✓ symbol.

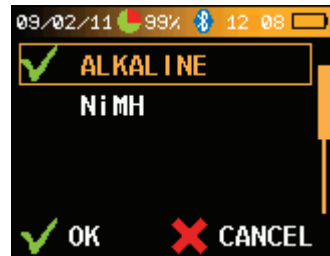


- When you have set the desired language select "OK. " If you want to cancel the language settings then select "CANCEL".

2.3.3 SETTING THE TYPE OF BATTERIES

It is very important that the type of batteries is correctly configured for the remaining battery life information to be displayed properly. Alkaline or rechargeable Nickel-Metal Hydride (minimum 2450mAh) AA batteries should be used. In the "CUSTOMIZE" screen follow these steps:

- Select "BATTERIES".
- Use ↑ and ↓ to select the type of batteries used in the device. The type of batteries is marked with the ✓ mark.
- When you have set the desired language select "OK. " If you want to cancel the language settings then select "CANCEL".



2.4 MAKING POLYGRAPHY TESTS


There are two different ways to start and stop the tests, either manually or automatically (scheduled).

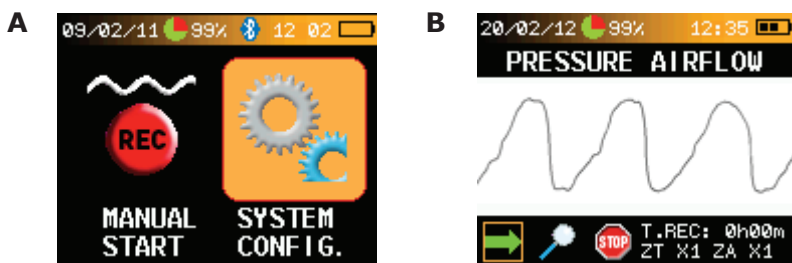
2.4.1 STARTING AND ENDING A TEST MANUALLY

In this mode either the patient or the technician will start and end the test:

- Switch on the device by pressing for 3 seconds the ON/OFF button.
- Once in the main screen press the joystick (A) to select the "MANUAL START" icon.
- This starts the recording of the test. If all sensors are properly connected then the signals are displayed on the screen and the LED on the front panel starts flashing. If any of the

sensors to be acquired is not properly connected the message "CHECK SENSOR" is displayed, giving the opportunity to test the connection. After a few seconds the screen switches off automatically.

- To stop the test just select the "STOP"  option or hold down the ON/OFF button for 3 seconds (B).







2.4.2 SCHEDULED TESTS

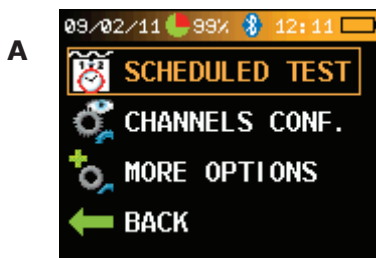
The Screen&Go is built with an internal clock suitable for scheduling new tests in holter mode at certain dates and times, which also end at the right time as programmed by medical personnel. In this way the patient does not have to interact at all with the Screen&Go for starting or ending the test.

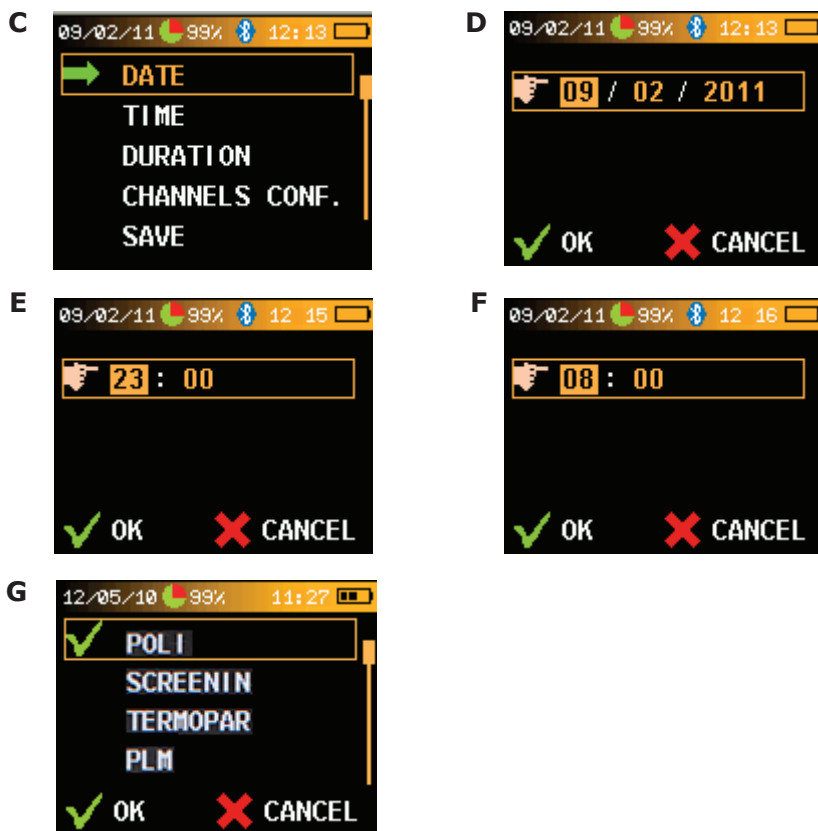
You can schedule up to 5 consecutive tests. These tests may be scheduled right from the Screen&Go device or by using the BitmedLab software in the PC. This manual describes the programming procedure in the Screen&Go. Refer to the software manual for information on the programming process in BitmedLab.

2.4.2.1 SCHEDULING A TEST IN THE SCREEN&GO

- Switch on the Screen&Go and gain access to the setup mode by making the following keystrokes on the joystick, one after another and leaving a short interval of time between each of them: , , , .
- Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.

- Select "SCHEDULED TESTS" (A).
- Select "NEW TEST" (B).
- Select the "DATE" field and set the starting date for the test. Select "OK" when finished (C, D).
- Select the "TIME" field and set the starting time for the test. Select "OK" when finished (E).
- Move to the "DURATION" field and enter the number of hours and minutes for the test (F).
- Select the option "CHANNELS CONF.". The device displays all channel configurations stored on the memory card. A channel configuration establishes which channels are recorded during the test, as well as their sampling rates. There may be up to 10 different channel configurations. A detailed explanation on how to change these configurations is given below. Select which configuration is more suitable for the type of test you want to do (G).
- Select "SAVE" once all parameters are configured. You may switch off now the Screen&Go.
- The device will start automatically the test at the designated date and time. The screen will light for 50 seconds, displaying the signals acquired by the sensors. The front panel LED will blink during the whole test.



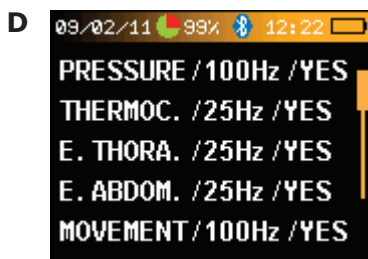
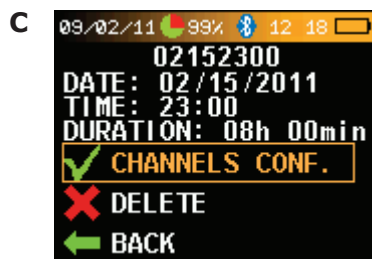
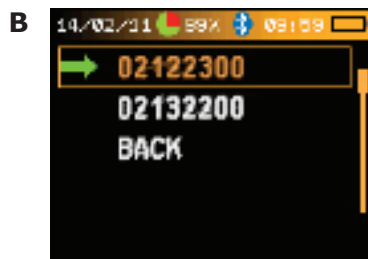
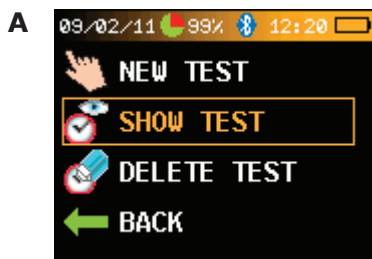


2.4.2.2 DISPLAYING THE SCHEDULED TESTS

You can see the scheduled tests in the Screen&Go (up to a maximum of 5 tests):

- Switch on the Screen&Go and enter the setup mode by making the following keystrokes with the joystick: ↓, ↓, ↑, ↑.
- Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.
- Select "SCHEDULED TEST".
- Select "SHOW TEST" (A).

- All scheduled tests are displayed. For more info on any scheduled test select it (B).
- The screen shows the programming data of the test (onset date and time, duration, channel configuration) (C).
- To view the channel configuration (enabled channels and sampling frequencies) select "CHANNELS CONF." (D).



2.4.2.3 CHANNEL CONFIGURATIONS

The Screen&Go may hold up to 10 channel configurations. Each configuration stores which of the available device's channels will be acquired, as well as the sampling rates for each of them. The available sample rates depend on each type of channel. Some channels, such as pulse oximetry or body position, have a fixed sampling frequency, while in others, such as the respiratory effort bands, the sampling rate can be chosen among several values.

The creation and modification of channel configurations is made in the BitmedLab software, then they are transferred to the MicroSD

memory card. See the software's manual for more information on this point.

2.5 TRANSFER AND REVIEW OF THE TESTS

Tests must be transferred to the PC prior to review. Several tests may be stored in the memory of the Screen&Go before transferring them to the PC. Transferring the test immediately after it is finished is not necessary.

In order to transfer the tests to the PC extract the MicroSD memory card from Screen&Go and insert it into your PC's card reader. Most computers are supplied by default with a memory card reader. If your computer does not have one you can use an USB card reader. After inserting the memory card in your PC run the BitmedLab software and download the tests as explained in the software's manual.

The tests are automatically deleted from the memory card when they are transferred to the PC. Do not delete the files in the memory card before downloading the tests to the PC.

2.6 FIRMWARE UPDATE

Over time, new versions of the program managing the Screen&Go (firmware) might be released, either to improve the operation of the equipment or to add new features.

- The Technical Service will provide one or several files to be copied to the MicroSD memory card of the Screen&Go.
- Insert the memory card in the Screen&Go and switch it on.
- The firmware update starts automatically. When prompted, confirm that you want to update the firmware.
- When the update is complete the Screen&Go switches off automatically. Your device is already updated.

- In case you are provided with several files the process will be repeated as many times as needed.

2.7 DEVICE OPTIONS UPDATE

As mentioned in paragraphs 1.2 and 1.3, the Screen&Go is delivered with just the airflow channel enabled. The available channels may be expanded, though. In case new features are purchased please follow these steps in order to update your device:

- The Technical Service will provide one file to be copied to the MicroSD memory card of the Screen&Go.
- Insert the memory card in the Screen&Go and switch it on.
- The update starts automatically. When prompted, confirm that you want to update the device's features.
- When the update is complete the Screen&Go switches off automatically. Your device is already updated and the new channels are available from now on.

3. TECHNICAL SPECIFICATIONS

3.1 GENERAL DATA

Useful life for Screen&Go:	7 years
Useful life for Xpod pulseoximeter module:	5 years
Battery type / battery life:	2x AA alkaline batteries or AA NiMH rechargeable batteries (2450mAh minimum) / >24h in holter mode.
Enclosure protection degree:	IP22
Memory type:	MicroSD
Device classification (EN60601-1):	Class: internally powered Type BF applied parts, not protected against defibrillator
Input impedance:	20 MW
CMRR (common mode rejection ratio):	>95dB
Signal input connectors:	<ul style="list-style-type: none"> • Pressure transducer (respiratory airflow, snore) • Polygraphic aux. • Pulse oximeter • Actimetry • Body position • Event marker <ul style="list-style-type: none"> • LUER connector. • 1 mm key connector. • Specific 3-pin connector. • Internal • Internal • Joystick

Storage sampling rate (software selectable):	<ul style="list-style-type: none"> • Airflow (pressure transducer) • Snore (pressure transducer) • Polygraphic aux. • Pulse rate • Oxygen saturation • Actimetry • Body position • Event marker 	<ul style="list-style-type: none"> • Selectable: 25, 50, 100 samples/s • Selectable: 50, 100, 250 samples/s • Selectable: 10, 25 samples/s • 1 sample/s • 1 sample/s • Selectable: 10, 25, 50 samples/s • 1 sample/s • 1 sample/s
Resolution:	<ul style="list-style-type: none"> • Resp airflow. (pressure transducer), snore (pressure transducer), polygraphic aux., actimetry • Pulse rate, oxygen saturation • Body position • Event marker 	<ul style="list-style-type: none"> • 12 bits • 8 bits • 8 bits • 8 bits
Sample storage size:	16 bits per sample	
Input range:	<ul style="list-style-type: none"> • Polygraphic aux. • Airflow (pressure transducer) • Snoring (pressure transducer) • Pulse • Oxygen saturation • Actimetry • Body position 	<ul style="list-style-type: none"> • +/-5 mVpp • +/- 4 cmH₂O (3.9 hPa) over the cannula approx. • +/- 0.5 cmH₂O (0.49 hPa) over the cannula approx. • 18 – 300 BPM (1/min) • 0 – 100 % • aprox. +/-30 mg (300 m/s²) • Supine, prone, left, right, seated
Linearity:	Resp. airflow (pressure transducer), snore (pressure transducer)	+/- 3%
	Polygraphic aux., actimetry	+/- 3%
Accuracy:		
Pulseoximeter	(See pulseoximeter table)	

Fixed hardware filters:	<ul style="list-style-type: none"> • Polygraphic aux. • Airflow (pressure transducer) • Snoring (pressure transducer) • Pulse • Oxygen saturation • Actimetry • Body position <ul style="list-style-type: none"> • 0.05 – 10 Hz • 0.05 – 50 Hz • 30 – 250 Hz • - • - • 0.5 – 25 Hz • - 	
Environmental conditions:	In operation	Transportation and storage
	Temperature: 5°C to 40°C Relative humidity: 15-93% (without condensation) Barometric pressure: 700hPa to 1060hPa (approx. 2950 to -350m)	Temperature: -20°C to +60°C Relative humidity: <93% (without condensation)
Dimensions:	90 x 90 x 25 mm	
Weight:	< 200 g	

1. All precision specifications were determined from studies of hypoxia induced in healthy adult volunteers, of both sexes, from Caucasian, Indian and African ethnic groups.
2. Standard Deviation. Due to the statistic distribution of the pulse oximeter measurements , only about two-thirds of the pulse oximeter measurements can be expected to be found within \pm Arms of the value measured by a CO-oximeter.

3.3 CONDITIONS OF OPERATION AND STORAGE OF ACCESSORIES

Although the device stands temperatures between -25 and 70 ° C, the specified temperature range is lower (-20 ° C and 60 ° C) in order to ensure the proper storage of all accessories.

3.4 APPLICABLE STANDARDS

The Screen&Go has the CE Marking (CE 0197). The CE mark is a statement that the Screen&Go fulfills the guidelines established by the EU for medical devices.

The Screen&Go is manufactured by SIBEL and the system (including the software) meets the following standards and regulations:

Recommendations:

- National consensus document on the apnea-hypopnea syndrome (SAHS). Spanish Sleep Group (GES), September 2005.
- The AASM Manual for the Scoring of Sleep and Associated Events, 2007

European Directive 93/42 EEC (R.D: 1591/2009):

- EC marking Class II a

Safety:

- EN 60601-1:2006+AC:2010: Electrical safety (3rd edition).
- EN 60601.1.11:2010 General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

EMC:

- EN 60601.1.2:2007+AC:2010 EMC in medical devices (No life support)

See **Annex 1 ELECTROMAGNETIC COMPATIBILITY**

Software:

- EN 62304:2006+AC:2008 Medical device software - Software life-cycle processes

Usability:

- EN 60601-1-6:2010 Medical Electrical Equipment – Part 1-6 General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 62366:2008 Medical Devices – Application of usability engineering to medical devices

Pulse oximetry:

- ISO 80601-2-61:2011 Special requirements for basic safety and essential operation characteristics of pulse oximeters for medical use

Biocompatibility:

- EN ISO 10993-1:2009+AC:2010 Biological evaluation of medical devices

Vibration and temperature:

- Levels according to EN 60601-1-11:2010 (covers ISO 80601-2-61)
- Tests according to EN 680068-2-27:1993 and EN 680068-2-64:1994

Environmental conditions:

- Levels and tests according to EN 60601-1-11:2010

Symbology:

- EN ISO 15223-1:2012 and EN980:2008 Symbols to be used with medical device labels, labelling and information to be supplied.

Packaging and labelling

- Packaging and packaging waste directive 94/62/EC
- Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (REACH)

Information supplied by the manufacturer:

- EN 1041:2008 Information supplied by the manufacturer of medical devices

Electrical and electronic waste:

- Electrical and electronic equipment and waste management. Transposition of the directive WEEE 2002/96/EC

System quality:

- Manufactured according to the SIBEL S.A. Quality Manual, which is compliant with EN ISO 13485:2012+AC:2012 and EN ISO 9001:2008

Risk Management:

- EN ISO 14971:2012

The user should follow:

- Data protection: Directive 95/46/EC
- 2002/96/EC

4. SYMBOLOGY

4.1 SYMBOLOGY OF THE SCREEN&GO



SERIAL NUMBER



MANUFACTURER (manufacture date, name and address of the manufacturer)



REFERENCE



CONSULT INSTRUCTIONS FOR USE



WARNING



START UP (STANDBY)



BF APPLIED PARTS



NO SPO₂ ALARMS



IP22 (see section WARNINGS AND PRECAUTIONS)



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC
ACORDING TO THE RAEE DIRECTIVE



BATTERIES

4.2 SYMBOLOGY OF THE ACCESORIES AND PACKAGING



CE MARKING



WARNING



DO NOT REUSE



BATCH NUMBER



REFERENCE



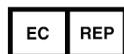
LATEX FREE



PHT (CONTAINS PHTHALATES)



MANUFACTURER (manufacture date, name and address of the manufacturer)



AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE RAEE DIRECTIVE



TEMPERATURE LIMITATION



SERIAL NUMBER



MANUFACTURING DATE



LATEX FREE



DO NOT STERILIZE



U.S. FEDERAL REGULATION RESTRICTS THIS DEVICE TO SALE
BY ORDER OF PHYSICIAN. MAY ALSO BE APPLICABLE IN OTHER
COUNTRIES



PHT (CONTAINS PHTHALATES), DEHP (CONTAINS DIETILHEXIL
PHTALATE)



HUMIDITY LIMITATION



USE BY



STACKING LIMITATION



THIS WAY UP



FRAGILE



KEEP AWAY FROM WATER



PREASURE LIMITATION

4.3 VALIDATED ACCESSORIES

The Screen&Go device is used in combination with other medical accessories manufactured by SIBEL S.A. or by other manufactures. We only recommend the use of these accessories for proper operation of the equipment (see section 1.2 PACKING LIST). The sensors used by other manufacturers are:

Accessory	Manufacturer	SIBEL reference	Manufacturer reference
THERMOCOUPLE SENSOR	S.L.P. INC.	06309	1401S-BI
SOFT PULSE OXIMETRY SPO ₂ SENSOR	UNIMED MEDICAL SUPPLIES INC.	08013	U101S-08
SOFT PULSE OXIMETRY SPO ₂ SENSOR	UNIMED MEDICAL SUPPLIES INC.	08012	U401S-08
DISPOSABLE NASSAL CANNULA	S.L.P. INC.	08049	15805-2-FT
DISPOSABLE PROTECH NASAL CANNULA (PACKAGE 60PC)	PRO-TECH	07679	P1328-60
DISPOSABLE PROTECH ORO-NASAL CANNULA (PACKAGE 30PC)	PRO-TECH	07680	P1343
DISPOSABLE SLEEPSENSE ORO-NASAL CANNULA (PACKAGE 5PC)	S.L.P. INC.	07681	14802-2-FT
DISPOSABLE SLEEPSENSE NASAL CANNULAR	S.L.P. INC.	08049	15805-2-FT
THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	S.L.P. INC.	06314	9102S-BI
FASTENING BELT SMALL SIZE (S)	S.L.P. INC.	06311	1348B
FASTENING BELT LARGE SIZE (L)	S.L.P. INC.	06312	1341
FASTENING BELT EXTRA LARGE SIZE (XL)	S.L.P. INC.	06313	1340
ELASTIC INDUCTIVE BAND SMALL SIZE (S)	S.L.P. INC.	01425	9002-L40
ELASTIC INDUCTIVE BAND MEDIUM SIZE (M)	S.L.P. INC.	01424	9002-L60
ELASTIC INDUCTIVE BAND LARGE SIZE (L)	S.L.P. INC.	01421	9002-L90
ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)	S.L.P. INC.	01420	9002-L120
ELASTIC INDUCTIVE BAND XTRA XTRA LARGE SIZE (XXL)	S.L.P. INC.	01417	9002-L150

5 CLEANING AND MAINTENANCE

The Screen&Go polygraph requires, like any electronic equipment, a maintenance in order to:

Ensure the safety of the patient, the operator and its environment.

Ensure the reliability and accuracy of the functions for which the Screen&Go was developed.

5.1 CLEANING

To clean the unit and its accessories, excluding the sensors, use a damp cloth and mild (hand) soap. To disinfect the device you can use alcohol (ethyl or isopropil). Do not use other chemical products or detergents for domestic use. Please read carefully the SAFETY section.

Properly dispose the disposable sensors immediately after use. Nasal cannulas are single use and must be replaced with each patient.

For the cleaning and disinfection of reusable sensors, please refer to the information provided by its manufacturer.



The device can not be sterilized. For the cleaning and disinfection of sensors, please refer to the information provided by its manufacturer.

All sensors should be cleaned properly after each use and before use in a new patient.

5.2 PREVENTIVE MAINTENANCE

Preventive maintenance consists of all actions needed to keep the equipment in good working order.

5.2.1 ACTIONS TO BE TAKEN BY THE USER

Check periodically that all cables, external accessories and other items are in perfect condition, not broken and with no external damage. Pay special attention to the cables and connectors.

It is also advisable from time to time to start a test and check that the connected sensors respond correctly.

If you detect any problems that you can not solve, please get in contact with the customer service of SIBEL S.A. or your distributor for servicing and repair.

You can also check the "Known abnormalities report" (534-701-MU2) available to the user from SIBEL S.A.

5.2.2 ACTIONS TO BE TAKEN BY QUALIFIED PERSONNEL

The Medical Device Directive 93/42/EEC recommends the regular servicing and / or calibration to ensure the reliability of the medical devices and the safety of patients, users and the environment. The general technical verification of safety systems, settings and features being part of the device, must be made according to the Procedure of Verification and Adjustment for the Screen&Go, of SIBEL S.A.

These operations must be carried out by service personnel from the manufacturer or distributor. The latter, must be in possession of a written authorization from SIBEL S.A., at least during the warranty period, in order to perform such maintenance.

The manufacturer is not responsible for malfunction or damage to the equipment resulting from poor maintenance done by personnel not certified in writing or belonging to SIBEL S.A.

Accessories and spare parts should always be original and requested to the manufacturer or authorized dealer to ensure the proper functioning of the polygraph.

Periodic functional and metrological verification is necessary to ensure the operation of equipment over the life of the product. The manufacturer recommends annual inspections by an authorized service center, and in any case not exceeding two years, according to the verification and adjustment procedures specified by the manufacturer and applied during the manufacture of the equipment.

5.3 CORRECTIVE MAINTENANCE

Corrective maintenance is the process of leaving the device in


good conditions of use when it stops working due to malfunction or misuse.

If you detect a fault in the equipment that prevents normal operation, please contact the SIBEL S.A. Customer Service Centre, specifying the type of problem suffered.

Annex 1. ELECTROMAGNETIC COMPATIBILITY

Manufacturer's guide and statement – electromagnetic emissions		
The SCREEN&GO/Screen&Go is designed to be used in the electromagnetic environment specified below. The customer or user must ensure that it is used within this environment.		
Emissions Test	Compliance level	Guide – Electromagnetic environment
Radiated RF Emissions CISPR 11 (EN 55011)	Group 1 Class B.	The SCREEN&GO/Screen&Go uses RF energy only for internal use. Therefore its emissions are very low and unlikely to cause any interference to nearby electronic devices.
Conducted RF Emissions CISPR 11 (EN 55011)	Not applicable	The SCREEN&GO/Screen&Go runs on batteries.
Harmonic Emissions EN-IEC 61000-3-2	Not applicable	The SCREEN&GO/Screen&Go runs on batteries.
Flicker and tension fluctuations EN-IEC 61000-3-3	Not applicable	The SCREEN&GO/Screen&Go runs on batteries.

Manufacturer's guide and statement –electromagnetic immunity			
The SCREEN&GO/Screen&Go is designed to be used in the electromagnetic environment specified below. The customer or user of the SCREEN&GO/Screen&Go must ensure that it is used in this environment.			
Immunity Test	Test level EN-IEC 60601	Compliance level	Guide - Electromagnetic environment
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV in contact ±8 kV in air	±6 kV in contact ±8 kV in air	The floor must be made of wood, cement or ceramic. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV feeder cables and earth lines ±1 kV for input/output lines	Not applicable Not applicable	The SCREEN&GO / Screen&Go runs on batteries. The length of the E/S lines is less than 3 m.
Surge EN-IEC 61000-4-5	±1 kV in differential mode ±2 kV in common mode	Not applicable Not applicable	The SCREEN&GO / Screen&Go runs on batteries.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % drop of Ut) for 0.5 cycles 40 % Ut (60 % drop of Ut) for 5 cycles 70 % Ut (30 % drop of Ut) for 25 cycles <95 % Ut (>5 % drop of Ut) for 5 seconds	Not applicable	The SCREEN&GO / Screen&Go runs on batteries.
Magnetic field 50 / 60 Hz EN-IEC 61000-4-8	3 A/m	3 A/m	The magnetic field in the room must be low enough to ensure the performance of the test.
Note: Ut is the alternating current power tension prior to the application of the test.			

Manufacturer's guide and statement –electromagnetic immunity			
The SCREEN&GO / Screen&Go is designed to be used in the electromagnetic environment specified below. The customer or user of the SCREEN&GO / Screen&Go must ensure that it is used in this environment.			
Immunity Test	Test Level EN-IEC 60601	Compliance level	Guide – Electromagnetic environment
Conducted RF EN-IEC 61000-4-6	3 Vrms from 150KHz to 80 MHz	3 Vrms	<p>Portable and mobile RF Communications units must be used no closer to any part of the SCREEN&GO / Screen&Go, including cables, than the recommended separation distance calculated for the equation applicable to the transmitter frequency.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E} \right] P \quad \text{from 80 MHz to 800 MHz}$ $d = \left[\frac{3.5}{E} \right] P \quad \text{from 80 MHz to 800 MHz}$ $d = \left[\frac{3.5}{E} \right] P \quad \text{from 800 MHz to 2.5 GHz}$ <p>where P is the maximum power output of the transmitter in watts (W) according to the manufacturer of the transmitter and d is the recommended separation distance in metres (m).</p> <p>Field intensities from permanent RF transmitters, determined by an electromagnetic measurement of the place a, must be less than the level of compliance in each margin of frequency b.</p> <p>Interferences may appear in the vicinity of units marked with this symbol:</p> 
Radiated RF EN-IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	3 V/m	
<p>Note 1. At 80 MHz and 800 MHz, apply the highest frequency margin.</p> <p>Note 2. These recommendations may not be applicable in all possible situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and persons.</p>			

- ^a The field intensities emitted by permanent transmitters such as base stations for radiotelephones (mobile-cell phones, wireless) and mobile radios, amateur radio operators, AM, FM radio and TV transmissions, cannot be theoretically calculated with any accuracy. To know the electromagnetic environment due to permanent RF transmitters, electromagnetic measurements of the place of use must be considered. If the field intensity of the place of use is superior to the level of compliance, it must be observed whether the behaviour of the SCREEN&GO / Screen&Go is normal. Otherwise, additional measurements such as the reorientation or change in placement of the SCREEN&GO / Screen&Go may be necessary.
- ^b Above the frequency range from 150 kHz to 80 MHz, the field intensity must be less than 3 V/m.

Recommended separation distances between mobile and portable RF communications units and the SCREEN&GO/Screen&Go

The SCREEN&GO/Screen&Go is designed to be used in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SCREEN&GO/Screen&Go can help to prevent interferences by keeping a minimum distance between mobile and portable RF communications units (transmitters) and the SCREEN&GO/Screen&Go as recommended below, according to the power output of the communications unit.

Maximum power output of the transmitter W	Separation distance depending on the transmitter frequency m		
	From 150 kHz to 80 MHz $d = \left[\frac{3.5}{E} \right] P$	From 80 MHz to 800 $d = \left[\frac{3.5}{E} \right] P$	From 800 MHz to $d = \left[\frac{3.5}{E} \right] P$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters with a maximum power output not listed above, the recommended separation distance d in metres (m) can be estimated using the applicable equation according to the transmitter frequency, where P is the maximum power of the transmitter in watts (W) according to the manufacturer of the transmitter.

Note 1 At 800 MHz, apply the highest frequency margin

Note 2 These recommendations may not apply in all possible situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and persons.

Annex 2. TROUBLESHOOTING GUIDE

The Screen&Go does not start

- Make sure the batteries are placed according to the polarity in the battery compartment.
- Be sure to use AA alkaline or NiMH rechargeable batteries of at least 2450mAh.
- Make sure you press the power button for at least 3 seconds.

In a new test the message "CHECK SENSOR" is displayed on screen

- Check that the erroneous sensor is correctly connected. If the problem is not solved after 5 minutes, the message will disappear.

Pulse oximetry signals are null

- Make sure the pulse oximeter sensor is correctly connected to the patient, as indicated the PLACEMENT OF SENSORS section.
- Make sure the pulse oximetry sensor connector is properly plugged into the top panel of the Screen&Go.
- Make sure the red light in the pulse oximetry sensor switches on when connected to the Screen&Go.